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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,657	09/18/2001	Richard E. Wooley	U022 1020.1	1163

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EXAMINER

YOUNG, MICAH PAUL

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 06/02/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/955,657	WOOLEY ET AL.
	Examiner	Art Unit
	Micah-Paul Young	1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

#### A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 07 March 2003.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

4) Claim(s) 1-16,18-22,54 and 55 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-16,18-22,54 and 55 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_

4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_

## DETAILED ACTION

**Acknowledgment of Papers Received:** Amendment and Response filed 3/7/03.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 3 – 5, 7, 8, 10, 12, 14, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Palladino et al (USPN 5,055,447). The claims are drawn to a method of treating a microbial infection in a skin wound. The method comprises applying a compound comprising an antimicrobial agent, a chelating agent, a pH buffer and a carrier. The claims recite specific chelating agents and antimicrobial agents all well known in the art. The claims also recite the skin wound to be a burn.

Palladino et al teaches a method of treating and preventing infections and septic shock in burn patients. The method comprising administering a compound comprising antimicrobial agents, chelating agents, carriers and a ph buffer. The antimicrobial agents are selected from a list consisting of amikacin, tobyramycin and gentamicin; the chelating agent is disclosed as EDTA, while sodium acetate acts as the buffer. Also the composition works against gram-negative bacteria such as *E. Coli* and *Pseudomonas aeruginosa* (Abstract; col. 5, lin. 40 – 57; col. 7, lin. 23 – 43, 61 – 68; Examples). These disclosures along with other render the claimed invention anticipated.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1 – 16, 18-22 and 54-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palladino et al (USPN 5,055,447) in view of Martin (USPN 5,863,938), Friedman et al (USPN 5,160,737), Azzariti (USPN 4,438,099), Nelson (USPN 4,323,558), and Huber et al (USPN 3,758,682).

6. As stated the claims are drawn to a method of treating a microbial infection in a skin wound in a patient. The method comprises applying a compound comprising an antimicrobial agent, a chelating agent, a pH buffer and a carrier. The claims recite specific chelating agents and antimicrobial agents all well known in the art. The claims also recite the skin wound to be a burn, ulcer or an abrasion. The composition further comprises vitamin E.

7. As discussed above Palladino discloses a method of treating infection comprising administering a composition comprising a chelating agent, an antimicrobial agent, a ph buffer

and a carrier. Palladino however does not disclose all of the antimicrobial agents as recited by applicant, nor does it disclose the same pH buffer as recited by applicant. Palladino also does not specify whether the agents were affective against specific Gram-positive bacteria. Another deficiency in the reference is its silence to the inclusion of vitamin E, or a possible form the composition can take such as a mouthwash.

8. With regard to the vitamin E limitation, it is common to include vitamins into topical wound healing preparations, to provide essential nutrients to the skin during the healing process or to act as a carrier for the healing composition. This is shown by Martin which teaches an antibacterial wound healing preparation which inhibits infection during the healing process by including antibiotics such as oxytetracycline, neomycin, and includes vitamin E (col. 11, lin. 29 – 55; col. 48, lin. 20 – 40). A skilled artisan is motivated to include such anti-oxidant agents into wound healing preparations in order to provide such properties to the composition and to provide nutrients to the wound site.

9. The remaining deficiencies are merely a matter of selecting equivalent or well-known species of components. Friedman teaches a method for treating an infection with a liquid polymer wound healing composition comprising neomycin, and other antibiotics. The composition has an embodiment, which treats oral mucosal wounds and is in the form of a mouthwash (col. 13, lin. 65 – col. 14, lin. 7; Examples). From this combination a skilled artisan would have expected the composition of Palladino to be able fight various infections unique to neomycin.

10. The selection of specific antibiotics because of their particular effectiveness against specific bacteria is well known in the art and is merely the selection of an equivalent species. As

seen in Azzariti, which teaches a method for treating infections in burns and ulcers, by using antibiotic agents which are active towards Gram-Positive bacteria such as *Staphylococcus* - (Examples), this practice of determining which bacteria are affected by which agents is well within the level of one of ordinary skill in the art, and does not impart patentability.

11. The selection of equivalent species continues in applicant's recitation of the chelating agents and the pH buffer. TRIEN is a well-known chelating agent in the art as seen in Nelson. Nelson teaches a composition for wound healing comprising TRIEN and various antibiotic agents such as penicillins, erythromycins and tetracyclines (col. 3, lin. 11 – 24; Examples). The selection of a pH buffer is well within the skill of the art, as seen in Huber et al which teaches a composition which has wound healing properties, which also included such antibiotics such as neomycin and or tetracyclines (col. 13, lin. 23 – 34). Substituting these two components a skilled artisan would have expected that the composition have an appropriate pH balance and an appropriate carrier composition suitable to provide stability to the formulation.

12. With this in mind a skilled artisan would have been motivated to follow the suggestions and teachings in the art in order to improve a method of treating or preventing infections in wounds. A skilled artisan would have combined the teachings of Palladino with those of Martin in order to include an antioxidant in the composition to provide a beneficial effect to the skin. A skilled artisan would have followed the suggestions of Friedman to combine these components together in order to treat oral injuries and inhibit bacterial infection in the form of a mouthwash. This artisan would have than simply selected equivalent species of well-known components such as the antibiotics and pH buffer of Huber, the chelating agent of Nelson, and the bacteria effecting knowledge shown in Azzariti. It would have been obvious to a skilled artisan at the

time of the invention to combine the knowledge and suggestions of these references with an expected result of a method for treating and preventing bacterial infection in wounds.

***Response to Arguments***

1. Applicant's arguments filed 3/7/03 have been fully considered but they are not persuasive. Applicant argues that:
  - a. Palladino does not disclose the synergistic relationship between the chelating agent and the antimicrobial agent.
  - b. None of the other reference cited disclose the synergistic relationship between the chelating agent and the antimicrobial agent.
  - c. There is no motivation to combine the cited references.

With regard to argument a., Palladino discloses a composition comprising a chelating agent, a pH buffer, and an antimicrobial agent. The fact that the chelating agent and antimicrobial agent are have a synergistic relationship is irrelevant to the patentability of the invention. Applicant makes a point that without this relationship the concentrations of the two components would be such to cause a negative effect in a patient, such as overdosing or toxic shock form the chelating agent. It is the position of the examiner that the mere selecting of proper concentrations can be determined through routine experimentation, and is simply an optimization of the parameters of the invention. These concentrations can be determined by a artisan of ordinary skill, and would require no undo experimentation to determine the appropriate concentration levels to be most beneficial to the patient.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on

combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). With regard to arguments b. and c., the supporting references were provided to show the use of the particular components of the invention through out the art. Martin provides the particular vitamin useful for the invention. Palladino has a general suggestion for the inclusion of vitamin in its composition. Martin provides the vitamin E, which would be beneficial to the treatment of the skin. Friedman and Azzariti provide composition and support for the use of particular antimicrobial agents, which can be substituted into the formulation of Palladino. Nelson provides the specific chelating agent which can substituted into the formulation of Palladino. Huber provides a specific pH buffer. All of these references support the suggestion and teachings of Palladino by providing specific components. The substitutions of these components into the composition of Palladino would be well within the level of skill in the art.

With regard to the applicant's argument that none of the references teach the topical administration claimed in the instant case. The examiner draws applicant's attention to column 6, lin. 44-47 of the Palladino reference. There, the reference states that any form of administration is acceptable for the composition of the references, including parenteral. This disclosure leave open a topical administration as a suitable application technique.

### ***Conclusion***

2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 703-308-7005. The examiner can normally be reached on M-F 7:30am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-7648 for regular communications and 703-746-7648 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Micah-Paul Young  
Examiner  
Art Unit 1615

MP Young  
May 30, 2003

CARLOS A. AZPURU  
PRIMARY EXAMINER  
GROUP 1500

